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STATE HEALTH PLAN
(August[~~April~~] 2020[~~November 2018~~])

CERTIFICATE OF NEED REVIEW STANDARDS

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Kentucky Cabinet for Health and Family Services

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Purpose, Authority, and Technical Notes

Purpose

The purpose of this document, which shall be referred to as the 2020-2022 [~~2018 Update to the 2017-2019~~] State Health Plan ("Plan"), is to set forth the review criteria that shall be used when reviewing applications for certificates of need for consistency with plans pursuant to KRS 216B.040; and for determining whether a substantial change to a health service has occurred pursuant to KRS 216B.015(29) and KRS 216B.061(1)(d).

Authority

KRS 216B.015(28) defines the "State Health Plan" to mean the document prepared triennially, updated annually, and approved by the governor.

KRS 216B.040(2)(a)2. requires the Cabinet for Health and Family Services ("Cabinet") to establish criteria for the issuance and denial of certificates of need and limits review to five considerations. The first consideration is "consistency with plans", which requires that "each proposal approved by the Cabinet shall be consistent with the State Health Plan, and shall be subject to biennial budget authorizations and limitations, and with consideration given to the proposal's impact on health care costs in the Commonwealth."

Technical Notes

1. Area Development Districts ("ADDs"), as referenced in the State Health Plan, are defined by KRS 147A.050.

2. The *Inventory of Kentucky Health Facilities, Health Services, and Major Medical Equipment* and utilization reports shall be available from the Office of Inspector General, Division of Certificate of Need at 275 East Main St., 5E-A, Frankfort, Kentucky, 40621, (502) 564-9592 and at Web Site: https://chfs.ky.gov/agencies/os/oig/dcn/Pages/cn.aspx.

3. All population estimates or projections for the Commonwealth of Kentucky used in a certificate of need application shall be obtained from the Kentucky State Data Center at website: http://ksdc.louisville.edu/.

Temporary Waiver of Certain Certificate of Need Requirements

Pursuant to the authority of KRS Chapter 39A, KRS 194A.025, and KRS 214.020, the Secretary of the Cabinet for Health and Family Services, as the Governor's designee, may temporarily waive Certificate of Need statutory and regulatory requirements established by KRS Chapter 216B, and 900 KAR Chapters 5 and 6, for certain transactions intended to increase access to critical health care services in the event of a State of Emergency. Waivers granted pursuant to this authority and as authorized by an Executive Order shall only be effective during a State of Emergency declared as the result of a public health crisis.

I. Acute Care

For purposes of this Plan, "Acute care" is defined as those medical or surgical services provided by an acute care hospital for the diagnosis or the immediate and continuous treatment for more than twenty-four (24) hours to individuals suffering from illness, disease, or injury.

A. Acute Care Hospital

Definitions

An "Acute Care Hospital" is defined as a facility providing medical or surgical services to all individuals that seek care and treatment, regardless of the individual's ability to pay for services. Acute care hospitals are capable of providing care on an immediate and emergent basis through an established Emergency Department as well as continuous treatment on its premises for more than twenty-four (24) hours. The facilities are licensed by the Cabinet for Health and Family Services, Office of Inspector General pursuant to 902 KAR 20:016. For the purposes of this section, the term "acute care hospital" shall not include critical access hospitals, which are licensed by the Cabinet for Health and Family Services, Office of Inspector General pursuant to 906 KAR 1:110.

A "Specialty Hospital" is defined as a facility offering limited, specialized medical or surgical services. These facilities are distinguishable from acute care hospitals because they do not provide an Emergency Department on a twenty-four (24) hour basis or are incapable of satisfying one (1) or more requirements for licensure pursuant to 902 KAR 20:016.

With regard to acute care hospitals, the "Planning Area" shall be comprised of the county of the proposed facility and all contiguous Kentucky counties.

The "Adjusted Revenue" is defined as the case mix adjusted net revenue per adjusted admission. The applicant shall utilize the most recent Medicare Cost Report data to calculate the following formula:

Adjusted Revenue = (Total Net Revenue/ADJ Admissions)/MCMI

Where:

Total Net Revenue = TGR - Contractual/Charity Allowances

TGR = Total Gross Revenue, which is:
Inpatient Gross Revenue + Outpatient Gross Revenue

IGR = Inpatient Gross Revenue

OGR = Outpatient Gross Revenue

ADJ Admissions = Adjusted Admissions = (TGR/IGR) • IA

IA = Inpatient Admissions

MCMI = Medicare Case Mix Index

Review Criteria

An application to establish a new acute care hospital shall be consistent with this Plan if the following criteria are met:

1. The applicant shall demonstrate that sufficient need for the proposed facility exists and that the establishment of the proposed facility would not result in the unnecessary duplication of services by documenting one (1) or more of the following:

    a. The overall occupancy of existing acute care beds in existing licensed acute care hospitals located in the planning area exceeds eighty (80) percent according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*;

    b. The adjusted revenue of each licensed acute care hospital located within the planning area exceeded 150 percent of the state mean adjusted revenue, for acute care hospitals, during each of the previous three (3) fiscal years; or

    c. All licensed acute care hospitals located within the planning area have experienced one (1) or more of the following:

        i. Final termination of their Medicare or Medicaid provider agreements;

        ii. Final revocation of the hospital license issued by the Cabinet for Health and Family Services, Office of Inspector General; or

        iii. Final revocation of their hospital accreditations by the Joint Commission on Accreditation of Healthcare Organizations;

2. The applicant shall demonstrate the ability to provide safe, efficient, and quality care and treatment to all individuals seeking medical or surgical services by documenting the following:

    a. Each individual responsible for the operation, management, and day-to-day control of the proposed facility has a documented history of providing healthcare services in conformity with federal and state standards. Moreover, no individual has had any license or certification denied, revoked, or involuntarily terminated, or has been excluded from participation in Medicare or Medicaid, or been convicted of fraud or abuse of these programs;

b. Written policies or protocols that implement measures to assure quality control with respect to the life, health, and safety of individuals seeking care and treatment at the proposed facility. These include documented plans of action that not only serve to prevent, but also identify, diagnose, control, and treat injuries or problems including the following:

   i. Acute myocardial infarctions sustained after arrival at the proposed facility;

   ii. Hospital-acquired infections;

   iii. Medication errors;

   iv. Hospital-acquired pneumonia;

   v. Death in low mortality Diagnosis Related Groups;

   vi. Re-admittance within twenty-four (24) hours of discharge;

   vii. Foreign objects not removed during surgical procedures;

   viii. Post-operative respiratory failure;

   ix. Post-operative sepsis;

   x. Decubitus ulcers;

   xi. Adverse reactions to the administration of medications or transfusions; and

   xii. Injuries sustained as a result of falls on the proposed facility's premises;

c. Written policies or protocols that implement measures to assure the proper use and utilization of all equipment to be maintained on the proposed facility's property that would be used in the care and treatment of potential patients;

d. Identification of the licensed physicians that would provide care and treatment to patients at the proposed facility. The applicant shall further demonstrate that the retention of these individuals would not adversely affect the clinical care and treatment offered at other licensed acute care hospitals located within the planning area; and

e. That the applicant has identified and would retain trained, experienced, and licensed personnel to provide efficient and effective clinical care and treatment to the proposed facility's patients. The applicant shall further demonstrate that the retention of these individuals would not adversely affect the clinical care and

treatment offered at other licensed acute care hospitals located within the planning area;

3. The applicant shall demonstrate the ability to provide cost-effective services by documenting the following:

   a. The proposed facility's payor mix would be comparable to all other licensed acute care hospitals located within the planning area; and

   b. A written business plan through which the economic performance and financial strength of the proposed facility would be comparable to the existing acute care hospitals located within the planning area. Specifically, the applicant shall document that its adjusted revenue would not exceed 150 percent of the state mean adjusted revenue;

4. The applicant shall demonstrate that the proposed facility would increase access to twenty-four (24) hour acute care and treatment by documenting the following:

   a. The proposed facility would provide care on an immediate and emergent basis through an established Emergency Department; and

   b. The proposed facility would provide emergency services to all individuals that seek care and treatment there, regardless of the individual's ability to pay for services;

5. The applicant shall demonstrate both its intention as well as its ability to provide the same or substantially similar clinical services offered by the existing acute care hospitals located within the planning area;

6. The maximum number of acute care beds that may be approved for the purpose of constructing or establishing a new acute care hospital shall be based on volume projected five (5) years from the filing of the application. Approval will be based on the higher of:

   a. The applicant's credible forecast of future utilization; or

   b. A regression analysis projection of patient day trends over a five (5) year timeframe;

7. The applicant shall obtain certificate of need approval for each service it proposes to offer by satisfying the review criteria for each service set forth within this Plan; and

8. An application for a specialty hospital shall not be consistent with this Plan.

B. Acute Care Beds

Definition

An "acute care bed" is defined as a hospital bed licensed by the Cabinet for Health and Family Services, Office of Inspector General. A hospital utilizes acute care beds in providing medical services, including physician services and continuous nursing services for the diagnosis and treatment of patients who have a variety of medical conditions, both surgical and non-surgical.

A "special purpose acute care bed" includes, but is not limited to, an Intensive Care Unit bed, Cardiac Care Unit bed, Neonatal Level II, Level III, or Level IV bed, and Obstetrics bed.

Review Criteria

An application to add additional acute care beds to an existing licensed hospital shall be consistent with this Plan if the following criteria are met:

1. The hospital shall document that transfer or conversion of special purpose acute care beds to acute care beds is not feasible because occupancy in the special purpose acute care beds is greater than sixty-five (65) percent or if the occupancy is less than sixty-five (65) percent, the transfer of beds would be insufficient to meet the hospital's total additional acute care bed need;

2. The hospital shall document that:

   a. Its annual acute care occupancy rate reported in the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* is higher than the occupancy rate set forth in Table 1 below; or

Table 1
Facility Acute Care Bed Occupancy Rates

Number of Licensed beds per Facility	Facility Acute Care Bed Annual Occupancy Percentage
1-50	60%
51 – 100	65%
101 – 200	70%
201 and above	75%

   b. Its utilization of acute care beds has reached functional capacity for the prior twelve (12) months. In calculating functional capacity, consideration shall be given to the percentage of licensed acute care beds, psychiatric beds, or chemical dependency beds currently operational as well as other factors affecting the utilization at the hospital including the mix of private and semi-private rooms, patient matching limitations such as gender or the need for isolation beds required

to address emergency patient needs, and limits created by special purpose acute care bed units; and

3. The maximum number of acute care beds that may be approved will be based on volume projected five (5) years from the date on which the hospital filed its application for additional acute care beds. Approval will be based on the higher of:

   a. The applicant's reasonable forecast of future utilization; or

   b. A regression analysis projection of patient day trends over a five (5) year timeframe.

C. Comprehensive Physical Rehabilitation Beds

Definition

For purposes of this Plan, there shall be one (1) category of rehabilitation beds called "comprehensive physical rehabilitation beds" that may be located in free-standing facilities or in units in acute care hospitals that provide therapy and training for rehabilitation. The facilities offer a range of services that may include occupational therapy, physical therapy, and speech therapy to aid in the restoration of an individual to normal or near normal function after a disabling disease or injury.

Review Criteria

An application for comprehensive physical rehabilitation beds shall be consistent with this Plan if the following criteria are met:

1. An applicant that does not have existing licensed or certificate of need approved comprehensive physical rehabilitation beds and is proposing to establish those beds shall demonstrate that the overall occupancy for comprehensive physical rehabilitation beds in the ADD exceeds seventy-five (75) percent as computed from the most recently published edition of the *Kentucky Annual Hospital Utilization and Services Report*;

2. An applicant proposing to expand the number of existing licensed comprehensive physical rehabilitation beds shall demonstrate that the occupancy of the existing comprehensive physical rehabilitation beds in the applicant's facility exceeds seventy-five (75) percent as computed from the most recently published edition of the *Kentucky Annual Hospital Utilization and Services Report*;

3. If criterion 1 or 2 is met, the maximum number of beds that may be approved in the ADD shall be computed by the following formula:

$$N = [((PD \div P) \times PP) \div (365 \times 0.75)] - (LB + AB)$$

Where:

N	=	Need for Comprehensive Physical Rehabilitation Beds in the ADD
PD	=	The number of inpatient days in comprehensive physical rehabilitation beds statewide as reported in the most recently published data
P	=	Estimated population in the Commonwealth for the period used to derive patient days
PP	=	Projected plan year population for the ADD
0.75	=	The desired average annual occupancy rate for comprehensive physical rehabilitation beds in the ADD
LB	=	Existing licensed comprehensive physical rehabilitation beds in the ADD
AB	=	The number of comprehensive physical rehabilitation beds in the ADD for which a certificate of need has been granted;

4. Notwithstanding criteria 1, 2, and 3, the Cabinet may approve more comprehensive physical rehabilitation beds than indicated by the need formula to allow for the presence of hospitals that provide a higher intensity of rehabilitation services than provided by most rehabilitation hospitals due to the in-migration of out-of-state patients or a high percentage of patient referrals for specialized services from other ADDs;

5. Notwithstanding criteria 1, 2, and 3, an application proposing to establish a comprehensive physical rehabilitation unit, within an existing acute care hospital with an existing licensed acute care bed inventory of at least 100 beds, shall be consistent with this Plan if the following criteria are met:

    a. There are no other licensed or certificate of need authorized comprehensive physical rehabilitation beds in the proposed ADD; or

    b. There are no other licensed or certificate of need authorized comprehensive physical rehabilitation beds within forty-five (45) highway miles of the proposed site;

6. Notwithstanding criteria 1, 2, and 3, an application proposing to add comprehensive physical rehabilitation beds to a Kentucky licensed comprehensive physical rehabilitation hospital or to a Kentucky acute care hospital with licensed comprehensive physical rehabilitation beds shall be consistent with this Plan if:

    a. The applicant's licensed comprehensive physical rehabilitation beds experienced greater than eighty (80) percent occupancy according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*; and

    b. The applicant documents that it is:

        i. An Inpatient Rehabilitation Facility participating in the Centers for Medicare & Medicaid Services IRF Quality Reporting Program that documents that its:

            (a) Percentage of patients with pressure ulcers that are new or worsened is equal to or better than the national average for the most recent IRF reporting period preceding the date the application is filed; and

            (b) Catheter associated urinary tract infection rate is equal to or better than the national average for the most recent IRF reporting period preceding the date the application is filed; or

        ii. An acute care hospital performing "no different than" or "better than" the most recently published U.S. National Benchmark preceding the date the application is filed for each of the following metrics:

(a) Catheter Associated Urinary Tract Infection rate; and

(b) Rate per 1,000 discharges of patients with a Stage III or IV hospital-acquired pressure ulcer (AHRQ PSI-3);

7. The maximum number of comprehensive physical rehabilitation beds that may be approved pursuant to criteria 4, 5, and 6 will be based on volume projected five (5) years from the date on which the hospital filed its application for the beds. Approval will be based on the higher of:

   a. The applicant's reasonable forecast of future utilization; or

   b. A regression analysis of patient day trends over a five (5) year timeframe; and

8. The minimum size for a new freestanding rehabilitation hospital shall be forty (40) beds and the minimum size for a new rehabilitation unit in an acute care hospital shall be ten (10) beds.

D. Special Care Neonatal Beds

Definition

"Special Care Neonatal beds" are licensed acute care beds located in hospital neonatal units that provide care and treatment of newborn infants through the age of twenty-eight (28) days, and longer if necessary. Special Care Neonatal Beds are categorized as Level II, Level III, or Level IV.

Review Criteria

An application for Level II, Level III, or Level IV Special Care Neonatal Beds shall demonstrate consistency with the most recently published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care* in regards to caring for the patients based on gestational age, weight, and need for advanced or specialty care.

An applicant for Level II or Level III Special Care Neonatal Beds shall include in their application a written affiliation agreement with at least one (1) provider who is located within the Commonwealth or in a contiguous state who meets Level IV criteria in the most recently published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care* and agrees to participate in a collaborative relationship as described in criterion 7.a. The affiliation agreement shall not preclude the ability of the hospital to transfer a sick infant to a different facility if that facility is an appropriate higher level of care.

An application to establish new Level II Special Care Neonatal beds or an application to add beds to an existing Level II service (not through the conversion of existing licensed beds) shall be consistent with this Plan if the following criteria are met:

1. Approval of the application does not cause the number of Level II beds to exceed the following calculation:

Maximum number of Level II beds in the ADD = (Total annual ADD births for the plan year ÷ 1000) • 4;

2. The number of Level II beds in a facility shall be eight (8) per unit except in those cases where population distribution and access to Level II services justify a smaller unit. In no case shall a unit be smaller than four (4) beds;

3. A new Level II program shall not be approved in an ADD unless the overall utilization of existing providers of Level II services in the ADD is at least seventy (70) percent as computed from the most recently published inventory and utilization data;

4. Additional beds (those not established through the conversion of existing licensed beds) shall not be approved for an existing unit unless the utilization in this unit is at least seventy (70) percent as computed from the most recently published inventory and utilization data;

5. The application documents consistency with the most recently published edition of the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists *Guidelines for Perinatal Care*;

6. An application for Level II special care neonatal beds shall document the ability to provide:

   a. All services required of a Level I basic care neonatal bed and Level II Special Care Nurseries outlined and described in the *Guidelines for Perinatal Care* including guidelines for inpatient care services based on gestational age and weight as well as ability to provide short-term ventilator services; and

   b. Detailed policies and procedures described in the *Guidelines for Perinatal Care* for the availability of obstetrics and neonatologists who are continuously available on site or able to be present within 30 minutes; appropriate equipment; appropriately trained personnel; and transfer agreements and procedures for infants born at < thirty-two (32) weeks gestation or who weigh < 1,500 grams at birth or when needed for pediatric surgical or medical subspecialty intervention;

7. Notwithstanding criterion 5, an applicant for Level II special care neonatal beds that will provide advanced care for stable or moderately ill newborn infants who are born at ≥ twenty-eight (28) weeks gestation, or who weigh ≥ 1200 grams at birth, or require ventilation for > twenty-four (24) hours shall:

   a. Provide documentation of a collaborative relationship with an eligible Level IV provider. The affiliation agreement shall be submitted with the application and specify the mutual responsibility for at least the following:

      i. Provision of consultation by the facility that provides Level IV services to the applicant for any infant born or anticipated to be born at the Level II facility at < thirty-two (32) weeks, < 1500 grams, or requiring ventilation for > twenty-four (24) hours to determine the most appropriate level of care for that infant;

      ii. Provision of education and training for perinatal health professionals of the applicant by the facility that provides Level IV services;

      iii. The joint development of guidelines for the provision and receipt of consultation between the parties for perinatal, neonatal, and other specialty disciplines as necessary;

      iv. The provision of consultation by the facility that provides Level IV services in the development, review, or revision of the applicant's

protocols, policies, and procedures related to:

(a) Maternal and neonatal patient referral and transport, including the process used by the referring facility to identify patients requiring transfer to a higher level of care;

(b) The care of the high risk obstetric and neonatal patients;

(c) The joint review of these polices at least every two (2) years;

(d) Joint development of guidelines for transferring a patient back to the referral facility when care needs can be adequately met by the referral facility; and

(e) Annual joint review of patient outcomes, including all deaths, complications, adverse outcomes {Very Low Birth Weight (VLBW), Bronchopulmonary Dysplasia (BPD), Retinopathy of Prematurity (ROP), Intraventricular Hemorrhage (IVH)} and patients requiring transfer to higher levels of care, with the development collaboratively of a plan of correction for areas where performance falls below expected levels; and agreement to allow technical assistance, including chart review, by the facility that provides Level IV services; and

v. Policies for the transfer to a higher level of care for patients that, at a minimum, meet the following:

(a) All premature infants under the gestational age or weight threshold;

(b) Patients needing to be transferred for evaluation or treatment by a pediatric specialist or subspecialist; or

(c) Patients requiring a higher level of respiratory support such as high frequency ventilation, nitric oxide, or extracorporeal membrane oxygenation;

b. Participate in the Vermont Oxford Network (VON), including the Kentucky State VON Report, and include a review of the hospital's data as part of the annual joint review of patient outcomes conducted in collaboration with the hospital's affiliated provider of Level IV services; and

c. Demonstrate readily available pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity;

8. Notwithstanding criterion 1, if the most recently published inventory and utilization data indicates that the occupancy of the applicant's existing Level II special care neonatal beds was seventy (70) percent or greater, an application to designate up to four (4) additional acute care beds as Level II special care neonatal beds shall be consistent with this Plan;

9. Notwithstanding criteria 1 and 3, if the most recently published inventory and utilization data indicates that the applicant had 700 or more annual births and that the average occupancy of the applicant's existing Level II special care neonatal beds over twelve (12) months was eighty (80) percent or greater, an application to establish up to eight (8) additional Level II or special care neonatal beds shall be consistent with this Plan;

10. Notwithstanding criteria 1 and 3, if the most recently published inventory and utilization data indicates that the applicant had 700 or more annual births, an application to establish a Level II program through conversion by designating up to eight (8) acute care beds as Level II special care neonatal beds shall be consistent with this Plan; and

11. Notwithstanding criterion 7, an applicant for Level II beds that currently provides Level IV services shall not be required to have a written affiliation agreement with a provider who meets Level IV criteria.

An application to establish new Level III Special Care Neonatal beds or an application to add beds to an existing Level III service (not through the conversion of existing licensed beds) shall be consistent with this Plan if the following criteria are met:

1. Approval of the application does not cause the number of Level III beds in the Commonwealth to exceed the following calculation:

(Total annual state births for the plan year ÷ 1000) ● 1 = Maximum number of Level III beds in the state;

2. An application for Level III special care neonatal beds shall document the applicant's ability to provide:

    a. All services required of a Level II Special Care Neonatal bed and Level III Special Care Nurseries (neonatal intensive care unit) as outlined and described in the *Guidelines for Perinatal Care* including continuous availability of personnel with specialized training; including neonatologists, neonatal nurses, and respiratory therapists; advanced monitoring, imaging, and treatment equipment; ongoing ventilation; and availability of maternal-fetal medicine specialists as well as other pediatric specialists and subspecialists;

    b. Readily available pediatric ophthalmology services in the Level III facility and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity;

    c. Documentation of the facility's participation in the Vermont Oxford Network

(VON), including the Kentucky State VON Report, and include a review of the hospital's data as part of the annual joint review of patient outcomes conducted in collaboration with the hospital's affiliated provider of Level IV services; and

d. Documentation of a collaborative relationship with an eligible Level IV provider. The affiliation agreement shall be submitted with the application and shall specify the mutual responsibility for at least the following:

i. Detailed explanation of any prearranged consultative agreements for pediatric medical subspecialists not available on site;

ii. Assurance that, when pediatric surgeons are not available on site, infants needing surgery are transferred to a site where all complex surgical procedures performed on newborn infants are performed by pediatric surgical specialists (including anesthesiologists with pediatric expertise);

iii. Assurance that referral to a higher level of care will occur for all infants requiring subspecialty intervention or surgical repair of complex conditions (e.g., congenital cardiac malformations that require cardiopulmonary bypass with or without ECMO); and

iv. Assurance of the availability of transport services to quickly and safely transfer infants requiring these subspecialty interventions to higher level facilities or children's hospitals; and

3. Notwithstanding criterion 2.d., an applicant for Level III beds that currently provides Level IV services shall not be required to have a written affiliation agreement with a provider who meets Level IV criteria.

An application to establish new Level IV Special Care Neonatal beds or an application to add beds to an existing Level IV service (not through the conversion of existing licensed beds) shall be consistent with this Plan if the applicant:

1. Is:

a. An academic medical center with a pediatric and neonatal training program that is accredited by the American College of Graduate Medical Education; or

b. A children's hospital with a pediatric and neonatal training program that is accredited by the American College of Graduate Medical Education;

2. Documents the ability to provide all services required of a Level III special care neonatal bed;

3. Documents the ability to provide pediatric medical subspecialists and pediatric surgical services within the institution, including anesthesiologists with pediatric expertise, as well as pediatric surgical subspecialists. These pediatric surgical subspecialist services, at

a minimum, shall include the ability to provide surgical repair of complex conditions;

4. Documents policies and procedures to facilitate transport systems and provide outreach education in their catchment area;

5. Documents capability to collect data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health services and the safety and efficacy of new therapies;

6. Documents consent to enter into collaborative relationships through written affiliation agreements with Level II neonatal facilities caring for stable or moderately ill newborn infants who are born at ≥ twenty-eight (28) weeks gestation or who weigh ≥ 1,200 grams at birth. An affiliation agreement shall specify the mutual responsibility for at least the following:

    a. Provision of education and training opportunities by the Level IV facility for perinatal health professionals;

    b. The joint development of guidelines for the provision and receipt of consultation between the parties for perinatal, neonatal, and other specialty disciplines as necessary; and

    c. The provision of consultation by the Level IV facility to the Level II facility in the development, review, or revision of the Level II facility's protocols, policies, and procedures related to:

        i. Maternal and neonatal patient referral and transport, including the process used by the Level II facility to identify patients requiring transfer to a higher level of care;

        ii. The care of the high risk obstetric and neonatal patients;

        iii. The joint review of these polices at least every two (2) years; and

        iv. Joint development of guidelines for transferring a patient back to the referral facility when care needs can be adequately met by the referral facility;

7. Documents consent to enter into a collaborative relationship through a written affiliation agreement with a Level III neonatal facility for the purposes of consultation, clinical expertise, education and training, and maternal and neonatal transfer; and

8. Documents commitment to:

    a. Participate in the Vermont Oxford Network (VON), including the Kentucky State VON Report, to ensure the capability to collect data and assess outcomes within the Level IV facility and to compare with other levels; and to provide an

annual report, which does not identify specific hospitals, to the Cabinet on aggregate statewide outcomes and trends based on the Kentucky State VON Report;

b. Establish a mortality and morbidity conference between Level III and Level IV facilities at least annually to review outcome data and identify opportunities for improvement;

c. Take the leadership role in establishing joint reviews with affiliated hospitals of patient outcomes, including all deaths, complications, adverse outcomes (VLBW, BPD, ROP, IVH), and patients requiring transfer to higher levels of care, at least annually;

d. Develop collaboratively with the affiliate facility a plan of correction for areas where performance falls below expected levels; and

e. Provide technical assistance, including chart review if needed, to assure areas of low performance show improvement.

E. Open-Heart Surgery Program

Definition

Open-heart surgery is any surgical procedure involving the heart, performed to correct acquired or congenital defects, to replace diseased valves, to open or bypass blocked vessels, or to graft a prosthesis or a transplant in place. In open-heart procedures, the heart chambers are open and fully visible and blood is detoured around the surgical field by a heart-lung bypass machine unless the procedure involved is a minimally invasive coronary artery bypass graft, in which case a heart-lung machine might not be used, but must still be available in the operating room on a stand-by basis.

A "case" is defined as the entire episode of treatment in the operating room regardless of the number of procedures performed.

Review Criteria

An application for an open-heart surgery program shall be consistent with this Plan if the following criteria are met:

1. For adult open-heart surgery, there is not an existing or approved open-heart surgery program in the ADD or the following criteria are met:

    a. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every open-heart surgery program in the ADD performed at least 400 adult open-heart surgeries;

    b. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every open-heart surgery program within a fifty (50) mile radius of the proposed site performed at least 400 adult open-heart surgeries;

    c. Every open-heart surgery program in the ADD that is not listed in the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* performed at least 300 adult open-heart surgeries in the past twelve (12) months;

    d. Every open-heart surgery program that is within a fifty (50) mile radius of the proposed site and is not listed in the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* performed at least 300 adult open-heart surgeries in the past twelve (12) months;

    e. The applicant shall document that at least 400 adult open-heart procedures will be performed during the third year of operation. These projections shall consider historical number of diagnostic cardiac catheterization procedures performed at the applicant hospital, the Kentucky statewide ratio of open-heart surgeries to diagnostic catheterization procedures as calculated in the latest published inventory and utilization data, and documentation of the number of diagnostic catheterization patients referred for open-heart surgery from the applicant hospital

during the most recent twelve (12) month period;

f. The applicant shall document that the approval of the proposed program will not cause any existing program in the ADD or any other open-heart surgery program within a fifty (50) mile radius of the proposed site to fall below 400 cases annually when considering historical trends in utilization, referral patterns for these services to existing providers, and commonality of medical staffs;

g. The applicant shall demonstrate that the projected number of therapeutic cardiac catheterization procedures will reach at least 350 by the third year of operation of the open-heart surgery program. These projections shall consider historical diagnostic cardiac catheterization procedures at the applicant hospital, the Kentucky statewide ratio of therapeutic catheterizations to diagnostic catheterizations, and documentation of the historical number of diagnostic cardiac catheterization patients referred from the applicant hospital for therapeutic cardiac catheterization during the most recent twelve (12) month period;

h. The applicant shall document that the most recently published *Guidelines for Coronary Artery Bypass Graft Surgery* adopted by the American College of Cardiology and the American Heart Association will be followed; and

i. The applicant shall identify the surgeon who will be the primary attending surgeon in the open-heart service. Further, the applicant shall also provide information regarding this individual's background and experience concerning open-heart surgery, and this individual's availability to care for open-heart patients in the event of emergencies; and

2. For pediatric open-heart surgery:

a. Only pediatric teaching facilities shall be approved for pediatric open-heart surgery;

b. According to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*, every existing pediatric program in the state shall be performing, and shall be projected to continue to perform, at least 150 pediatric open-heart surgeries per year; and

c. The applicant shall document that at least 100 pediatric open-heart procedures will be performed during the third year of operation.

F. Organ Transplant Program

Definition

Transplant procedures involve the transfer of an organ or tissue from one (1) person to another, or from one body part to another, to replace a diseased structure, to restore function, or to change appearance. Skin and kidneys are among the more commonly transplanted structures; others include hearts, livers, lungs, pancreas, cartilage, bone marrow, corneal tissue, portions of blood vessels, and tendons.

Review Criteria

An application for an organ transplant program shall be consistent with this Plan if the following criteria are met:

1. The applicant documents that the number of transplants being performed by comparable transplant programs in the Commonwealth are sufficient for consistency with nationally accepted volume and quality standards for each type of transplant program; the record of medical outcomes by those programs; and the impact on need for additional transplant programs in Kentucky resulting from the existence of transplant programs in nearby cities of bordering states that are customarily and significantly used by Kentucky residents;

2. The applicant documents that it has the ability to meet nationally accepted volume and quality standards, as well as those factors that impact patient care and overall cost, quality, and outcomes of service delivery, including demographic and epidemiological factors;

3. For pediatric programs, the pediatric program shall be provided in a pediatric teaching facility that has the availability of physician specialty support and specialized ancillary support services; and

4. The applicant demonstrates that organ allocation for patients awaiting transplantation shall be performed in accordance with federally mandated guidelines.

II. Behavioral Health Care

A. Psychiatric Beds

Definition

"Allocated psychiatric beds" are those beds licensed as general psychiatric beds and designated by the licensee for use as adult psychiatric beds or child or adolescent psychiatric beds at the discretion of the licensee.

"Psychiatric beds" are those licensed beds that are located in psychiatric hospitals or in units in an acute care hospital or a critical access hospital and are used for treatment of inpatients that require psychiatric or mental health care, including medical care and treatment of mental, emotional, and behavioral disorders.

Review Criteria

An application for psychiatric beds shall be consistent with this Plan if the following criteria are met:

1. Licensed and approved adult and geriatric psychiatric beds in an ADD shall not exceed 0.2 beds per 1,000 geographic adult and geriatric population for the plan year. Licensed and approved children or adolescent psychiatric beds in an ADD shall not exceed 0.2 beds per 1,000 geographic child and adolescent population for the plan year. Statewide psychiatric care facilities operated or contracted by the Commonwealth shall not be counted in the existing bed count;

2. Any existing acute care facility or psychiatric hospital proposing the addition of adult psychiatric beds shall exceed the target occupancy rates shown in Table 1 below for its licensed and allocated adult psychiatric care beds for the most recent twelve (12) month period reported in the most recently published edition of the *Kentucky Annual Hospital Utilization and Services Report* unless all the proposed additional psychiatric care beds are being converted from licensed acute care beds;

Table 1

Facility Target Psychiatric Bed Occupancy Rates

# Beds in Facility	Target Occupancy
1-50	60%
51-100	65%
101-200	70%
201 and above	75%

3. Additional adult psychiatric beds shall not be approved for purposes of establishing a new facility or a new unit unless occupancy for each facility with licensed and allocated adult psychiatric beds in the ADD exceeds the target occupancy rates shown in Table 1 according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*;

4. Any existing acute care facility or psychiatric hospital proposing the addition of child or adolescent psychiatric beds shall exceed the target occupancy rates shown in Table 1 of Criterion 2 for its licensed and allocated child or adolescent psychiatric care beds for the most recent twelve (12) month period reported in the most recently published edition of the *Kentucky Annual Hospital Utilization and Services Report* unless all the proposed additional psychiatric care beds are being converted from licensed acute care beds;

5. Additional child or adolescent psychiatric beds shall not be approved for purposes of establishing a new facility or a new unit unless occupancy for each facility with licensed and allocated child or adolescent psychiatric beds in the ADD exceeds the target occupancy rates shown in Table 1 according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report*;

6. If the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* indicates that the occupancy for existing psychiatric beds for an applicant's facility was seventy (70) percent or greater, an application to convert acute care beds to psychiatric beds shall be consistent with this Plan if the application meets either of the following conditions:

    a. The applicant meets criteria 1, 2, and 3 or criteria 1, 4, and 5; or

    b. The applicant has existing licensed acute care beds and psychiatric beds; and:

        i. All of the proposed psychiatric beds are being converted from licensed acute care beds;

        ii. The occupancy of acute care beds is less than seventy (70) percent in the latest published utilization and inventory data; and

        iii. The additional psychiatric beds will be converted and implemented on-site at the applicant's existing licensed acute care facility;

7. If the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report* indicates that the occupancy for existing psychiatric beds for an applicant's facility was seventy (70) percent or greater, an application to convert chemical dependency beds to psychiatric beds shall be consistent with this Plan if the application meets either of the following conditions:

    a. The applicant meets criteria 1, 2, and 3 or criteria 1, 4, and 5; or

    b. The applicant has existing licensed chemical dependency beds and psychiatric

beds; and:

i. All of the proposed psychiatric beds are being converted from licensed chemical dependency beds;

ii. The conversion will not impede access to appropriate care for patients needing treatment for abuse or addiction to chemical substances such as alcohol or drugs; and

iii. The additional psychiatric beds will be converted and implemented on site at the applicant's existing licensed acute care or chemical dependency facility;

8. The maximum number of psychiatric care beds that may be approved shall be based on volume projected five (5) years from the filing of the application. Approval shall be based on the higher of:

   a. The applicant's credible forecast of future utilization; or

   b. A regression analysis projection of patient day trends over a five (5) year timeframe;

9. Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application to add psychiatric beds to an existing licensed psychiatric unit or psychiatric hospital shall be consistent with this Plan if the applicant demonstrates that its utilization of its existing psychiatric beds has reached functional capacity for the prior twelve (12) month period. In calculating functional capacity, consideration shall be given to the following:

   a. The percentage of licensed acute care beds, psychiatric beds, or chemical dependency beds currently operational;

   b. The type and level of psychiatric care being provided at the applicant's facility;

   c. The historical performance as it relates to the utilization of psychiatric beds; and

   d. The availability of other providers of psychiatric services in the ADD; and

10. Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application by a licensed psychiatric hospital for the conversion to psychiatric beds of the psychiatric hospital's licensed tuberculosis beds shall be consistent with this Plan if the conversion does not increase the total licensed bed capacity of the psychiatric hospital.

Psychiatric Services for Children and Adolescents

In addition to the above criteria, an application for child or adolescent psychiatric beds shall be consistent with this Plan if the following criteria are met:

1. The applicant shall provide clear descriptions of which evidence-based practices will be utilized and how they will meet the clinical needs of the proposed population to be served;

2. New hospital psychiatric beds for children or adolescents shall focus on short-term (under thirty (30) days) crisis stabilization. Small, specialized programs are preferred over larger programs;

3. A facility proposing to provide inpatient psychiatric care for children twelve (12) years of age and younger shall have on staff a board-eligible or board-certified child psychiatrist who maintains responsibility for admissions and treatment. For the purposes of this section, a board-eligible child psychiatrist is a doctor of psychiatry who has been board-certified in general psychiatry by the American Board of Psychiatry and Neurology and has completed a two (2) year fellowship in child psychiatry; and

4. An application for new psychiatric beds for children or adolescents shall include all of the following:

    a. The specific number of beds proposed for each age group;

    b. An inventory of all facilities with child or adolescent psychiatric beds in the ADD and the number of beds;

    c. Clear admission and discharge criteria consistent with a short-stay program and least restrictive treatment;

    d. Linkage agreements with other child and adolescent serving agencies in the proposed service areas, including all regional interagency councils (RIACs), community mental health centers, the Department for Community Based Services, and major referring school systems. These agreements shall demonstrate a commitment by these agencies and the hospital to joint treatment and discharge planning as appropriate;

    e. Documentation of linkage agreements for the provision of case management services when necessary after discharge. (Case managers are not required to be on the hospital's staff, but shall be closely involved in cases from treatment planning onward); and

    f. Documentation of the policies and procedures to ensure a case manager will be identified and an appointment scheduled as part of the discharge planning process; and in the case of a child, the case manager shall be involved in the discharge planning process.

Geriatric Psychiatric Services

An application to establish non-Medicaid inpatient geriatric psychiatric programs in an existing

licensed acute care or critical access hospital located in a county that has no existing inpatient geriatric psychiatric program shall be considered consistent with this Plan if the following conditions are met:

1. If the applicant is an acute care hospital, the occupancy of acute care beds in the applicant's facility is less than seventy (70) percent according to the most recent edition of the *Kentucky Annual Hospital Utilization and Services Report;*

2. If the applicant is an acute care hospital, all of the proposed psychiatric beds are being converted from licensed acute care beds;

3. All of the psychiatric beds will be implemented on-site at the applicant's existing licensed facility;

4. All of the psychiatric beds shall be dedicated exclusively to the treatment of geriatric patients, aged sixty-five (65) or older;

5. The applicant establishes distinct admission and discharge criteria for admitting only those patients who have both mental and physical conditions who would be excluded from treatment in a regular adult psychiatric unit;

6. The staff of the unit shall include a multidisciplinary team of specialists involving psychiatry and internal medicine with specialization in the treatment of geriatrics and nursing personnel specially trained in psychiatric and medical geriatric patient care; and

7. The applicant agrees in writing not to seek Medicaid certification for the geriatric psychiatric beds.

B. Psychiatric Residential Treatment Facility

Definition

"Psychiatric residential treatment facility" or "PRTF" means either a licensed:

Level I community-based, and home-like facility with a maximum of nine (9) beds that provides inpatient psychiatric residential treatment to residents age six (6) to twenty-one (21) years who have an emotional disability or severe emotional disability as defined by KRS 200.503, with an age range of no greater than five (5) years at the time of admission in a living unit; or

Level II home-like facility that provides twenty-four (24) hour inpatient psychiatric residential treatment and rehabilitation to persons who:

1. Are ages four (4) to twenty-one (21) years, with an age range of no greater than five (5) years at the time of admission to the facility;

2. Have a severe emotional disability as defined by KRS 200.503 in addition to severe and persistent aggressive behaviors, intellectual disability, sexually acting out behaviors, or developmental disability; and

3. Do not meet the medical necessity criteria for an acute care hospital or a psychiatric hospital and whose treatment needs cannot be met in an ambulatory care setting, Level I psychiatric residential treatment facility, or other less restrictive environment.

"Specialty Program" means a program offered by a Level II psychiatric residential treatment facility to treat a person who has a severe emotional disability as defined by KRS 200.503 in addition to severe and persistent aggressive behaviors, intellectual disability, sexually acting out behaviors, or developmental disability.

Review Criteria

Level I PRTF

An application to establish a Level I PRTF or expand an existing Level I PRTF shall be consistent with this Plan if the following criteria are met:

1. Approval of the application does not cause the total number of Level I PRTF beds to exceed 315 beds statewide;

2. The applicant shall document the need for additional Level I PRTF services and its ability to provide those services by demonstrating the following:

    a. An analysis of the number and characteristics of persons ages six (6) to twenty-one (21) in the proposed service area who require this level of care;

    b. The defined geographic service area that the proposed facility will serve;

c. The anticipated average length of stay, average daily census, and occupancy rate;

d. The projected payor mix of the patients;

e. The anticipated referral sources including the projected number of Department for Community Based Services (DCBS) children in state custody who would be admitted; and

f. Clear admission and discharge criteria with specific descriptions of any special defining characteristics of the population that is proposed to be served, including age, sex, developmental status, legal status, and diagnostic characteristics;

3. The applicant shall include an inventory of all types of treatment oriented residential programs including other Level I PRTFs that serve children ages six (6) to twenty-one (21) in the proposed service area and how the proposed facility or additional beds fit into the array of current services;

4. The applicant shall clearly describe the treatment planning and the discharge planning process, including how the family or legal guardian would be included in the treatment and discharge process. For children in state custody, describe how DCBS staff will be included in the treatment and discharge planning process. For children who attain age twenty-one (21) that need to be transitioned to the adult system, describe the transition and discharge planning process to the adult system;

5. The applicant shall provide clear descriptions of which evidence based clinical practices will be utilized and how they will meet the clinical needs of the proposed population to be served;

6. Applicants shall describe the types and qualification of personnel required to provide services, including certification specific to the programs being proposed, and a detailed description of the availability of qualified staff;

7. The applicant shall provide a description of the proposed facility, physical layout, description of individual unit sizes, and proximity to other programs and facilities that might be housed on the same campus or in close proximity, either operated by the same applicant or other organizations, or demonstrating clearly defined relationships;

8. The applicant shall provide a description of how the proposed Level I PRTF's individual living units and program spaces will provide a safe environment and be community based and home-like in physical appearance and structure, but also in terms of family visitation policies and contact with significant adults in the residents' lives;

9. An application to establish a Level I PRTF shall include formal written agreements of cooperation that identify the nature and extent of the proposed working relationship between the facility and the following agencies, organizations, or entities located in the

primary service area of the proposed facility:

a. Regional interagency council for services to children with an emotional disability created under KRS 200.509;

b. Community board for mental health or individuals with an intellectual disability established under KRS 210.380;

c. The Department for Community Based Services;

d. Local school districts in the county where the PRTF is located;

e. At least one (1) psychiatric hospital; and

f. Linkages with other child and adolescent serving agencies in the proposed service area; and

10. Priority shall be given to applicants that demonstrate the capacity to provide or have access to a full array of other community-based services, and applicants that demonstrate the adoption of system of care principles and the wraparound process that includes family driven and youth guided programming and treatment.

Level II PRTF

An application to establish a Level II PRTF or expand an existing Level II PRTF shall be consistent with this Plan if the following criteria are met:

1. The application to establish a Level II PRTF does not exceed fifty (50) Level II PRTF beds;

2. Approval of the application to expand an existing Level II PRTF does not cause the existing Level II PRTF to exceed fifty (50) Level II PRTF beds in a facility;

3. The applicant shall:

a. Fully describe the specific Specialty Program to be provided and the target population to be served in the proposed Level II PRTF, including each specific age and gender;

b. Specify the defined geographic service area that the proposed facility will serve;

c. Indicate the specific number of beds proposed for each age group and specific Specialty Program, based on diagnoses, that the Level II PRTF is proposing to offer;

d. Document the anticipated average length of stay, average daily census, and

occupancy for each age group and Specialty Program;

e. Document the projected payor mix of the patients, including Medicaid and DCBS children in state custody;

f. Document the need for Level II PRTF beds requested, based on historical patient data from patients that have been sent out of state or other substantiated data, to demonstrate the need for Level II PRTF services and the number of beds and type of specialty program services proposed; and

g. Document clear admission and discharge criteria for each specialty program proposed, including age, sex, developmental status, legal status, and diagnostic characteristics;

4. The applicant shall include an inventory of Level II PRTFs that serve children ages four (4) to twenty-one (21) in the proposed service area and how the proposed facility or additional beds will fit into the array of current services;

5. The number of beds requested for each specialized program shall be calculated using an annual average occupancy rate of seventy-five (75) percent;

6. The applicant shall document that the facility or program shall not refuse to admit a patient who meets the medical necessity criteria and facility criteria for Level II PRTF services;

7. The applicant shall clearly describe the treatment planning and the discharge planning process, including how the family or legal guardian would be included in the treatment and discharge process. For children in state custody, describe how the Department for Community Based Services (DCBS) staff will be included in the treatment and discharge planning process. For children who attain age twenty-one (21) that need to be transitioned to the adult system, describe the transition and discharge planning process to the adult system;

8. The applicant shall provide clear descriptions of which evidence based clinical practices will be utilized and how they will meet the clinical needs of the proposed specialty population to be served and how staff will be trained and supervised, and how accuracy to the evidence based practice will be monitored;

9. The applicant shall describe the types and qualification of personnel required to provide services, including certification specific to the programs being proposed, and a detailed description of the availability of qualified staff and how the facility will immediately obtain additional staff as may be needed to ensure the safety of patients;

10. The applicant shall provide a description of the proposed facility, physical layout, description of individual unit sizes, and proximity to other programs and facilities that might be housed on the same campus or in close proximity, either operated by the same

applicant or other organizations, or demonstrating clearly defined relationships;

11. The applicant shall provide a description of how the proposed Level II PRTF's individual living units and program spaces will provide a safe environment and be home-like in physical appearance and structure, but also in terms of family visitation policies and contact with significant adults in their lives;

12. An application to establish a Level II PRTF shall include formal written agreements of cooperation that identify the nature and extent of the proposed working relationship between the facility and the following agencies, organizations, or entities located in the primary service area of the proposed facility:

    a. Regional interagency council for services to children with an emotional disability created under KRS 200.509;

    b. Community board for mental health or individuals with an intellectual disability established under KRS 210.380;

    c. The Department for Community Based Services;

    d. Local school districts in the county where the PRTF is located;

    e. At least one (1) psychiatric hospital, if the applicant is not a psychiatric hospital or an acute care hospital that provides inpatient psychiatric services for adolescents or children; and

    f. Linkages with other child and adolescent serving agencies in the proposed service area;

13. In approving a Level II PRTF application, consideration shall be given to the geographic location and specialty program offered by the proposed facility to ensure that Level II PRTF specialty programs are provided in different geographic areas of the State; and

14. Priority shall be given to applicants that demonstrate the capacity to provide or have access to a full array of other community-based services, and applicants that demonstrate the adoption of system of care principles and the wraparound process that includes family driven and youth guided programming and treatment.

III. Long-Term Care

A. Nursing Facility Beds

Definition

"Nursing Facility Bed" includes long-term care beds licensed as Alzheimer beds, intermediate care beds, nursing facility beds, and nursing home beds.

Nursing Facility Beds do not include personal care beds, nursing home beds established as part of a continuing care retirement community (CCRC), or long-term care beds located in state or federally-operated facilities.

Need Assessment for Nursing Facility Beds

The need for additional nursing facility beds in each county shall be calculated as follows:

$$\mathbf{A = B - C}$$

Where:

A = The net county NF bed need.

B = The number of patients from the applicant's proposed county of location who found NF bed placement in a noncontiguous Kentucky county as reported in the most recently published *Kentucky Annual Long-Term Care Services Report*.

C = The average number of empty beds in the county of application and all Kentucky counties contiguous to the county of application. The average number of empty beds for a county shall be calculated by multiplying the number of non-state owned and non-CCRC licensed NF beds times the occupancy percentage for the county as reported in the most recently published *Kentucky Annual Long-Term Care Services Report*.

Review Criteria

An application for nursing facility beds shall be consistent with this Plan if the following criteria are met:

1. The number of nursing facility beds being applied for is equal to or less than the net county NF bed need;

2. Any approval shall give preference to conversion of personal care beds and acute care beds to nursing facility beds so long as the conversions are more cost effective than new construction;

3. Notwithstanding criteria 1 and 2, an application to transfer or relocate licensed or existing certificate of need approved nursing facility beds shall be consistent with this Plan if the following criteria are met:

   a. The proposed transfer or relocation is within the same county, to a contiguous county, or to a county within the same Area Development District; and

   b. The transfer of licensed nursing facility beds does not result in a need for additional nursing facility beds in the county of the transferring facility using the State Health Plan methodology for net county nursing facility bed need;

4. Notwithstanding criteria 1 and 2, an application submitted to transfer licensed nursing facility beds to a licensed long term care facility as defined in KRS 216.510 (excluding family care) in a county that is not contiguous or to a county outside the Area Development District shall be consistent with this Plan if the following criteria are met:

   a. More than ten (10) nursing facility beds shall not be transferred from a licensed nursing facility within a period of one (1) year;

   b. The facility transferring the beds is located in a county that has an average annual nursing facility bed occupancy of <95% as reported in the most recently published *Kentucky Annual Long-Term Care Services Report*;

   c. The facility receiving the beds is located in a county that has an average annual nursing facility bed occupancy of ≥95% annual occupancy as reported in the most recently published *Kentucky Annual Long-Term Care Services Report*; and

   d. The transfer of licensed nursing facility beds does not result in a need for additional nursing facility beds in the county of the transferring facility using the State Health Plan methodology for net county nursing facility bed need; and

5. Notwithstanding criteria 1, 2, 3, and 4, an application submitted by an existing facility that has met the emergency circumstances provision established in 900 KAR 6:080, Section 2, and has received notice from the Office of Inspector General, Division of Certificate of Need, that an emergency exists shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating an emergency specific to ventilator-dependent patients that require long-term ventilator services.

B. Home Health Agency

Definitions

A "Home Health Agency" is defined by KRS 216.935(2).

“To establish a home health service” means to establish a parent home health agency or a subunit as defined by Medicare in a county where the applicant is not currently licensed to serve.

"To expand a home health service" means to add to the applicant's existing service area a Kentucky county or counties that are contiguous to the applicant’s existing service area if the expansion does not involve the establishment of a parent home health agency or subunit as defined by Medicare.

Summary of Need Criteria

The need for home health services is determined on a county-by-county basis by applying target rates estimating the number of individuals per 1,000 population expected to require home health services. Age cohort target rates are calculated for the plan year and are based on the average number of unduplicated patients served statewide in each age cohort for the most recent two (2) calendar years in the *Kentucky Annual Home Health Services Report*. Age cohort rates are applied to the plan year county population projections to determine expected need for home health services. The number of additional patient services needed in a county is then determined by subtracting the average number of unduplicated patients served in the county for the most recent two (2) calendar years, as reported in the *Kentucky Annual Home Health Services Report*, from projected need.

The inventory for patients expected to be served will be adjusted by the addition of 250 patients for each certificate of need approved to establish a new agency or subunit in a specific county, by 125 patients for each application approved to expand a home health service to a specific county, and by fifty (50) patients for each application approved for a hospital to establish an agency to solely serve the county in which the hospital is located. The respective number of patients will be removed from the inventory for patients to be served when the latest edition of the *Kentucky Annual Home Health Services Report* indicates that the agency has served patients in the approved county. The inventory for patients expected to be served shall not be adjusted to reflect certificate of need approvals that were restricted to the limited purpose of alleviating an emergency.

Review Criteria

1. An application to establish a home health service shall be consistent with this Plan if there is a projected need for at least 250 additional patients needing home health care services in the county for which the application is made as shown in the most recent edition of the *Kentucky Annual Home Health Services Report*;

2. An application to expand a home health service currently licensed in Kentucky shall be

consistent with this Plan if there is a projected need for at least 125 additional patients needing home health care services in the county for which the application is made as shown in the most recent edition of the *Kentucky Annual Home Health Services Report*;

3. Notwithstanding criteria 1 and 2, an application submitted by an existing home health agency that has met the emergency circumstances provision as established in 900 KAR 6:080, Section 2, and has received notice from the Office of Inspector General, Division of Certificate of Need that an emergency exists shall be consistent with this Plan only if the application is restricted to the limited purpose of alleviating the emergency; and

4. Notwithstanding criteria 1 and 2, an application by a licensed Kentucky acute care hospital, critical access hospital, or nursing facility proposing to establish a home health service with a service area no larger than the county in which the facility is located and contiguous counties proposing to service exclusively patients discharged from its facility shall be consistent with this Plan if the facility documents, in the last twelve (12) months, the inability to obtain timely discharge for patients who reside in the county of the facility or a contiguous county and who require home health services at the time of discharge.

C. Hospice Services

Definition

"Hospice Services" provide symptom relieving care and supportive services through an interdisciplinary approach that addresses the physical, spiritual, social, and economic needs of terminally ill patients and their families. Services include home care, inpatient care, bereavement services, counseling, and education. Emphasis is placed on symptom control and pain control for the terminally ill person, support for the patient before death, and support for the family before and after death.

Need Assessment for Hospice Services

The need for additional Hospice Services shall be calculated on a county-by-county basis as follows:

$$\textbf{HPR} = \frac{\textbf{(Year (n) Admissions * 0.50) + (Year (n-1) Admissions * 0.30) + (Year (n-2) Admissions * 0.20)}}{\textbf{(Year (n) Deaths * 0.50) + (Year (n-1) Deaths * 0.30) + (Year (n-2) Deaths * 0.20)}}$$

Where:

HPR	=	Hospice Penetration Rate
Year (n)	=	Year of the most recently published report
Year (n-1)	=	Year of the second most recently published report
Year (n-2)	=	Year of third most recently published report
Admissions	=	Unduplicated hospice admissions utilizing data published in the three (3) most recent editions of the *Kentucky Annual Hospice Services Report*
Deaths	=	Deaths from all causes (excluding deaths resulting from suicide, homicide, or unintentional injuries) as reported in the three (3) most recent editions of the Kentucky Department for Public Health, *Vital Statistics Report*

Review Criteria

An application to establish or expand hospice services shall be consistent with this Plan if:

1. a. The hospice penetration rate in the proposed county is less than eighty (80) percent of the median hospice penetration rate statewide; and the proposed county is located in an ADD where the mean hospice penetration rate of the counties within the ADD is less than eighty (80) percent of the median hospice penetration rate statewide;

b. Each approved hospice agency in the proposed county has been operational for at least thirty-six (36) months; and

c. Only one (1) application for hospice services may be approved in each county during any batching cycle; and

2. Notwithstanding criterion 1, an application to establish or expand hospice services into an individual county shall be consistent with this Plan if the applicant documents the existence of at least one (1) of the following conditions:

a. Absence of services by a hospice certified for Medicaid and Medicare in the proposed county, and evidence that the applicant will provide Medicaid and Medicare-certified hospice services in the county; or

b. Absence of services by a hospice in the proposed county that serves patients regardless of the patient's ability to pay, and evidence that the applicant will provide services for patients regardless of ability to pay.

D. Residential Hospice Facility

Definition

A "Residential Hospice Facility" is licensed pursuant to 902 KAR 20:380 and provides residential care for terminally-ill patients that includes skilled nursing care for the management of pain and acute and chronic symptoms.

Review Criteria

An application to establish a residential hospice facility shall not be approved under this Plan.

E. Intermediate Care Facility for Individuals with an Intellectual Disability

Definition

"Intermediate Care Facility for Individuals with an Intellectual Disability" or "ICF/IID" provides services for all age groups on a twenty-four (24) hour basis, seven (7) days a week, in an establishment with permanent facilities including resident beds for persons whose mental or physical condition requires developmental nursing services along with a planned program of active treatment. The facility provides special programs as indicated by individual care plans to maximize the resident's mental, physical, and social development in accordance with the normalization principle.

Review Criteria

An application for a new ICF/IID shall not be consistent with this Plan unless it is limited to a transfer of ICF/IID beds from an existing ICF/IID facility to the proposed ICF/IID facility. An application to increase the number of beds at an existing ICF/IID facility shall not be consistent with this Plan unless the increase in beds is accomplished by transferring beds from an existing ICF/IID facility. **[~~Beds from a public ICF/IID facility shall not be transferred to a proposed or existing private ICF/IID facility.~~]**

IV. Diagnostic and Therapeutic Equipment and Procedures

A. Cardiac Catheterization Service

Definition

"Cardiac Catheterization" is a diagnostic or therapeutic procedure in which a catheter is introduced into a large vein or artery, usually of an arm or a leg, and threaded through the circulatory system to the heart. To determine the number of cardiac catheterization procedures performed, each administrative claims record submitted pursuant to KRS 216.2920 – 216.2929 and 900 KAR 7:030 is examined to determine if it contains procedure codes indicating diagnostic catheterization or therapeutic catheterizations as defined below. Inpatient Hospital Discharge records are examined for ICD-10 Procedure codes as published in the most recent Professional Edition ICD-10-CM Manual for Hospitals Volume 3, while Outpatient Services Records are examined for CPT Procedure codes as published in the most recent Professional Edition Current Procedural Terminology Manual. As published in the *Annual Administrative Claims Data Report – Cardiac Catheterization,* diagnostic includes a count of the number of administrative claims records where the record included a Diagnostic Code regardless of the presence of any additional Therapeutic code. Therapeutic includes a count of the number of administrative claims records where the record included a Therapeutic Code regardless of the presence of any additional Diagnostic code.

"Diagnostic" cardiac catheterization means providing diagnostic only cardiac catheterizations on an organized, regular basis, in a laboratory. The term includes the intra coronary administration of drugs; left heart catheterization; right heart catheterization; coronary angiography; diagnostic electrophysiology studies; and cardiac biopsies (echo-guided or fluoroscopic).

"Therapeutic" cardiac catheterization means a classification of invasive procedures in which a slender tube is passed into a peripheral vein or artery, through the blood vessels, and into the heart to treat and resolve anatomical or physiological problems in the heart. These procedures are intended primarily for the treatment of cardiac disease. The term includes percutaneous coronary intervention (PCI), percutaneous transluminal coronary angioplasty (PCTA), atherectomy, and stent. The use of clot-dissolving infusion drugs approved by the FDA such as Streptokinase and TPA does not constitute the provision of therapeutic cardiac catheterization.

With regard to cardiac catheterization services, the term "Laboratory" means each dedicated room within a fixed-site facility that is individually equipped and staffed for the purposes of performing cardiac catheterizations.

With regard to cardiac catheterization services, the "Planning Area" shall be comprised of the county of the proposed cardiac catheterization program and all contiguous counties.

Review Criteria

An application proposing to provide cardiac catheterization services shall be consistent with this Plan if the following criteria are met:

1. For all cardiac catheterization laboratories, the applicant shall maintain a utilization review program (including record keeping) relating to medical necessity, quality, mortality, morbidity, number of cardiac catheterizations that require repetition due to inability to read the data, and other considerations generally accepted as appropriate for review;

2. For all cardiac catheterization laboratories, the applicant shall document that the most recent national guidelines as established by the Ad Hoc Task Force on Cardiac Catheterization of the American College of Cardiology/American Heart Association and published in ACC/AHA Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories will be followed. This report sets guidelines for administration, space, equipment, personnel, and working arrangements for diagnostic and therapeutic cardiac catheterization laboratories;

3. For applicants proposing fixed site diagnostic cardiac catheterization only:

    a. The applicant is licensed by the Cabinet for Health and Family Services, Office of Inspector General as an acute care hospital pursuant to 902 KAR 20:016;

    b. According to the most recent edition of the *Kentucky Annual Administrative Claims Data Report – Cardiac Catheterization*, each existing fixed-site diagnostic laboratory in the planning area shall have performed at least 250 adult diagnostic procedures in the last twelve (12) month reporting period. Each existing fixed-site comprehensive **laboratory** **[~~program~~]** [~~laboratory~~] (diagnostic and therapeutic) shall have performed at least 550 adult procedures in the last twelve (12) month reporting period;

    c. The total projected number of adult diagnostic catheterizations in the planning area shall exceed the total existing adult procedures by at least 250 procedures by the end of the third year of operation.

        i. The total projected number of adult procedures will be based on the adult diagnostic cardiac catheterization use rate for the Commonwealth of Kentucky for the most recent twelve (12) month period for which data are published in the *Administrative Claims Data Report – Cardiac Catheterization* applied to the projected planning area population three (3) years in the future from the date the application was filed; and

        ii. The number of diagnostic cardiac catheterization procedures performed by existing programs, according to the most recent edition of the *Kentucky Annual Administrative Claims Data Report – Cardiac Catheterization,* will be subtracted from the total projected diagnostic procedures for the

planning area. If there are approved fixed-site laboratories not included in the most recently published *Kentucky Annual Administrative Claims Data Report – Cardiac Catheterization*, an additional 250 procedures will be subtracted from the total for each fixed-site laboratory; and

d. The applicant has established a cardiology program as evidenced by the availability of at least two (2) board certified cardiologists with medical staff privileges at the applicant's hospital;

4. An applicant that is licensed to provide fixed site diagnostic cardiac catheterizations proposing to expand its services to also provide fixed site therapeutic cardiac catheterizations limited to primary (i.e. emergency) and elective Percutaneous Coronary Intervention (PCI) services shall meet the following criteria:

a. The applicant shall be an existing licensed Kentucky acute care hospital;

b. The applicant shall have performed, according to the most recent edition of the *Kentucky Annual Administrative Claims Data Report - Cardiac Catheterization*, an average of at least 200 annual diagnostic cardiac catheterization procedures during the previous two (2) years;

c. The proposed service shall be staffed with the following:

i. Experienced nursing and technical laboratory staff with training in interventional laboratories who are comfortable treating acutely ill patients with hemodynamic and electrical instability;

ii. Coronary care unit nursing staff experienced and comfortable with invasive hemodynamic monitoring, operation of temporary pacemaker, management of temporary pacemaker, and management of intra-aortic balloon pump (IABP), management of in-dwelling arterial/venous sheaths and identifying potential complications such as abrupt closure, recurrent ischemia, and access site complications;

iii. Personnel capable of endotracheal intubation and ventilator management both on-site and during transfer if necessary;

iv. A program director, whether located on-site or based at a facility with a comprehensive cardiac surgical program, who shall have performed at least 500 career PCI procedures over a life time, have performed a minimum of 150 PCI procedures in the previous year, and be board certified by the American Board of Internal Medicine in interventional cardiology;

v. Operators that shall have American Board of Internal Medicine (ABIM) board certification in interventional cardiology and maintain certification,

with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams; and

vi. Interventional cardiologists who shall have performed a minimum of fifty (50) coronary intervention procedures per year, averaged over a two (2) year period, to maintain competency;

d. The primary PCI services shall be available on a continuous twenty-four (24) hour per day basis;

e. Support services including respiratory care, blood bank, intensive care, advanced imaging, and nephrology consultation with access to dialysis shall be available;

f. The application shall contain a current, signed agreement for emergency transfer of patients to a collaborating tertiary hospital that has an active comprehensive cardiac surgical program (including open-heart surgery) within the facility. This agreement shall commit the collaborating tertiary facility to the following:

i. Provide continuous twenty-four (24) hours per day availability of consultation to the physician and nursing staff of the applicant's participating hospital in the care of patients that are candidates for or have received primary or elective angioplasty;

ii. Establish cardiopulmonary bypass on emergency transfer patients within 120 minutes of an urgent referral;

iii. Develop and participate in a joint performance improvement program, with the participant hospital, which includes all disciplines (i.e., physicians, nurses, and technicians from the staffs of both the applicant's participating hospital and the collaborating facility) providing patient care and focusing on patient outcomes;

iv. Develop and participate in joint in-service education programs for all staff (including physicians, nurses, and technicians) at the collaborating hospital. The in-service education programs will be based upon needs identified in the processes of staff evaluation and the performance improvement program; and

v. Collaborate with the applicant's participating hospital to undergo peer review of the first 150 therapeutic cardiac catheterization procedures through the Joint Performance Improvement Committee. A peer review shall be conducted for all patients who were either transferred to the tertiary hospital or experienced an adverse outcome as defined by the ACC;

g. The applicant shall maintain a cardiac catheterization laboratory equipped with high-resolution digital imaging capability and IABP equipment compatible with transport vehicles. Additionally, the applicant and the collaborating tertiary facility shall have an image transfer system in place with capabilities for immediate consultation between the applicant's cardiologist and the collaborating facility's cardiothoracic surgeon or interventional cardiologist;

h. The applicant shall maintain an inventory of interventional equipment, including guide catheters, balloons, and stents in multiple sizes; thrombectomy and distal protection devices; covered stents; temporary pacemakers; and pericardiocentesis trays. The applicant shall have access to intravascular ultrasound and fractional flow reserve;

i. The applicant shall maintain an ST-segment elevation myocardial infarction (STEMI) system of care in accordance with the most recent SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site Surgical Backup;

j. The applicant shall maintain an ongoing program for data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review, including without limitation tracking door-to-balloon times and other metrics set forth in the most recent SCAI/ACC/AHA Expert Consensus Document on PCI Without On-Site Surgical Backup;

k. The applicant shall participate in the American College of Cardiology National Cardiovascular Data Registry;

l. The applicant shall have an agreement with an ACLS-capable ambulance service stating that the service will respond to a call from that facility in no greater than thirty (30) minutes and arrive at the collaborating facility within sixty (60) minutes of the decision to declare the need for emergency surgery. The ambulance service shall also meet all American College of Cardiology (ACC) requirements for transporting heart patients and provide evidence that EMS or air transport has the capability to transport a patient with a balloon pump;

m. The applicant shall obtain consent from each patient that informs the patient that the PCI is being performed without on-site surgical backup and acknowledges the possibility of risks related to transfer. The consent shall include the risk of urgent surgery (approximately 0.3%) and state that a written plan for transfer exists; and

n. The PCI program shall project at least 200 annual PCIs and that each interventional cardiologist shall perform an average of at least fifty (50) annual coronary intervention procedures during the second year of operation;

5. For an applicant that is licensed to provide fixed site diagnostic cardiac catheterization services proposing to expand its services to also provide therapeutic catheterizations beyond PCI only, the applicant shall also document that:

a. Training for percutaneous transluminal coronary angioplasty (PTCA) will follow the guidelines set forth in the Bethesda Conference on Adult Cardiology Training (Journal of the American College of Cardiology, 1986; 7: 1191-218), as revised, which require extra training beyond the two (2) years for clinical cardiology; and

b. Each physician is projected to perform at least seventy-five (75) successful angioplasties per year with acceptable mortality and morbidity in patients who warrant the procedure;

6. For applicants proposing a pediatric cardiac catheterization laboratory, the facility shall also offer a pediatric cardiac surgical program and a Level IV neonatal intensive care unit;

7. Notwithstanding criteria 1, 2, 3, 4, 5, and 6, an application to establish a comprehensive (diagnostic and therapeutic) cardiac catheterization service shall be consistent with this Plan if:

a. The applicant is a licensed Kentucky acute care (non-critical access) hospital affiliated with the cardiology program of the primary teaching facility of the University of Kentucky or the University of Louisville (collectively "Kentucky academic medical center") through a formal affiliation in the form of an agreement or a contract in place for at least two (2) years and specifically focusing on improving cardiology care in the service area or county of the applicant hospital;

b. The medical director and the cardiologists staffing the applicant's proposed cardiac catheterization service will be affiliated with the cardiology program of the primary teaching facility of a Kentucky academic medical center;

c. The applicant hospital is located within fifty (50) highway miles of the primary teaching facility of a Kentucky academic medical center;

d. The applicant hospital is located in a county that does not have an existing cardiac catheterization service and has a population greater than 30,000; and

e. The applicant hospital has a minimum of 20,000 emergency department encounters on an annualized basis;

8. An application to establish a mobile cardiac catheterization service shall not be approved under this Plan; and

9. Notwithstanding criteria 1, 2, 3, 4, 5, 6, 7, and 8, an application to establish a fixed-site diagnostic cardiac catheterization service shall be consistent with this Plan if the following criteria are met:

a. The applicant is an acute care hospital that is providing diagnostic cardiac catheterization with intermittent equipment through a mobile license; and

b. The applicant is proposing to replace the mobile service at its hospital with a fixed-site, diagnostic cardiac catheterization service.

B. Megavoltage Radiation Equipment

Definition

"Megavoltage Radiation Equipment" is used in the treatment of cancer. For the purposes of this Plan, megavoltage radiation equipment includes units such as linear accelerators that operate at two (2) or more megavolts and deliver external radiation.

A "Megavoltage Radiation Therapy Program" is defined as a licensed megavoltage radiation therapy service or a megavoltage radiation therapy service that is not currently licensed but was issued a certificate of need within the previous three (3) years.

With regard to megavoltage radiation equipment, the "Planning Area" shall be comprised of the county of the proposed megavoltage radiation therapy program and all contiguous Kentucky counties.

Review Criteria

An application for megavoltage radiation therapy services shall be consistent with this Plan if the following criteria are met:

1. a. The number of procedures performed in the proposed planning area is greater than the sum of 4,000 per megavoltage radiation therapy program with only one (1) megavoltage radiation therapy unit and 8,000 per megavoltage radiation therapy program with two (2) or more megavoltage radiation therapy units, as reported in the latest edition of the *Kentucky Annual Megavoltage Radiation Services Report*; and

   b. The applicant shall demonstrate that sufficient need exists for that program to perform a minimum of 6,000 annual procedures by the end of the second year of operation;

2. Notwithstanding criterion 1, an application proposing to establish a megavoltage radiation therapy program limited to image-guided robotic linear accelerator-based stereotactic radiosurgery shall be required to demonstrate only that sufficient need exists for that program to perform a minimum of 1,000 annual procedures by the end of the second year of operation; and

3. Notwithstanding criterion 1, an application to establish a megavoltage radiation service that will be majority-owned (>50%) by a Kentucky hospital accredited by the American College of Surgeons Commission on Cancer as an Academic Comprehensive Cancer Program shall be consistent with this Plan.

C. Positron Emission Tomography Equipment

Definition

"Positron Emission Tomography" or "PET" scans combine nuclear scanning with chemical analysis to enable physicians to observe how organs work. Positrons are positively charged electrons that are produced spontaneously as certain radioactive substances (for example, radioactive glucose) decompose. The type of radioactive substance used for a particular PET scan varies, based on the medical condition for which a patient is being tested. During a PET scan, the radioactive material is introduced into the patient's body (usually by injection) and is detected by a sophisticated camera that obtains sectional views through a patient's body.

A "PET Procedure" is defined as a PET diagnostic scan or combination of scans performed on a single patient in a single session.

A "PET Program" is defined as a licensed or certificate of need approved service utilizing one (1) or more PET units at a single location by a single owner.

A "mobile PET Scanner" means a PET scanner and transporting equipment that is moved to provide services at two (2) or more host facilities.

With regard to PET equipment, the "Planning Area" shall be comprised of the county of the proposed PET program and all contiguous Kentucky counties.

Review Criteria

An application for PET services shall be consistent with this Plan if the following criteria are met:

1. Applicants proposing to establish a fixed-site PET unit shall project a minimum of at least 900 procedures in the first full year of operation and 1,200 procedures per year by the second full year of service and annually thereafter;

2. Applicants proposing to establish or expand a mobile PET service shall project a minimum of at least 540 mobile procedures within the Commonwealth in the first full year of service and at least 720 procedures within the Commonwealth per year by the second full year of service and annually thereafter;

3. The application shall document a projection of need for the PET unit that shall include demographic patterns, including analysis of applicable population-based health status factors, estimated utilization by patient clinical diagnoses category (ICD-10), and documentation demonstrating that the applicant is providing or has referral arrangements with other medical providers that offer comprehensive cancer and cardiac diagnostic and treatment services;

4. Approval of the application does not cause the number of licensed or certificate of need approved fixed-site PET programs to exceed one (1) per 100,000 population in the proposed planning area; and

5. Notwithstanding criteria 1, 2, 3, and 4, an application submitted to establish or expand a mobile PET service shall be consistent with this Plan if the applicant provides documentation of an arrangement to provide services to a licensed acute care hospital or critical access hospital in the planning area and has the support of that hospital.

D. New Technology

Definition

"New Technology" includes new technological equipment or services not previously provided in the Commonwealth and not otherwise covered in this Plan that involve a capital expenditure that exceeds the capital expenditure minimum or equipment that exceeds the major medical equipment minimum, and has an annual operating cost greater than $500,000, or new technology where the medical literature indicates that certain utilization levels or procedural volumes are necessary to achieve desirable patient outcomes.

Review Criteria

Preference shall be given to proposals that involve multi-institutional arrangements by contract, agreement, ownership, or other means between two (2) or more agencies to coordinate services, share support services, or provide services on a geographically integrated basis. A party to a multi-institutional arrangement shall not establish its own service or participate in another arrangement for the service until the original service is operating at sufficient capacity for adequate efficiency and quality of care. If the projected use of the new service includes expected referrals from others, the referring parties shall be included in the multi-institutional arrangement, if possible.

Preference shall be given to proposals that place the new technology in a medical school or other teaching or research facility. New technology designed or proposed for pediatric use shall be approved only in pediatric teaching facilities that have the availability of physician specialty support and specialized ancillary support services.

An application for new technology shall be consistent with this Plan if the following criteria are met:

1. The applicant shall document that the proposed new technology is efficacious;

2. The applicant shall document that the equipment is certified for its proposed use by the United States Food and Drug Administration (FDA);

3. Before acquiring new technological equipment, an applicant shall have complementary diagnostic and treatment services available to support the new program;

4. In cases where specific professional standards have not yet been formulated, an applicant shall demonstrate that personnel who will staff the new technology are qualified and adequately trained. The applicant shall specify how personnel will be trained in the use of the specific equipment and safety procedures to follow in the event of an emergency. The institution providing the new services shall document its plan for providing continuing education for referring physicians and institutions in the use of the new technology; and

5. An applicant acquiring new technological equipment shall report utilization and demographic data necessary to evaluate the technology and to facilitate state planning.

E. Magnetic Resonance Imaging Equipment

Definitions

"Magnetic Resonance Imaging" or "MRI" means a diagnostic imaging modality that utilizes magnetic resonance, an interaction between atoms and electromagnetic fields, to produce images of internal body structures.

Review Criteria

An application to establish an MRI service shall be consistent with this Plan if the applicant documents that the proposed MRI service shall be:

1. Consistent with the American College of Radiology (ACR) accreditation requirements; and

2. Accredited by the American College of Radiology (ACR) within twelve (12) months of licensure.

V. Miscellaneous Services

A. Ambulance Service

Definition

"Ground ambulance services" means services provided by a Class I, II, III, or IV ground ambulance transport agency. The license classifications are established in KRS 311A.030 and 202 KAR 7:545.

Review Criteria

An application for ground ambulance services shall be consistent with this Plan if the following criteria are met:

1. The applicant shall document that all agencies licensed to provide ambulance service or medical first response within the applicant's proposed geographic service area have been given notice of the applicant's intent to obtain a certificate of need. The notice shall describe the scope of service and proposed geographic service area with specificity; and

2. In the event of competing applications to add services in the same service area, preference shall be given to an application proposing the higher level of service. If multiple providers propose advanced life support (ALS) services, then preference shall be given to the applicant who most thoroughly documents need for the service and presents ability to meet the need.

B. Ambulatory Surgical Center

Definition

An "Ambulatory Surgical Center" or "ASC" is a free standing or hospital based health facility where scheduled procedures that are billed as surgical procedures, to include cystoscopy procedures, are performed. An ASC shall meet the licensure requirements of 902 KAR 20:106 and 902 KAR 20:101.

Review Criteria

An application for outpatient surgical services that will result in the establishment of an additional licensed ASC shall be consistent with this Plan if the following criteria are met:

1. Overall inpatient and outpatient surgical utilization in hospitals and ASCs is at least eighty-five (85) percent in the planning area as computed from the most recent editions of the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Services Report*. With regard to ambulatory surgical services, the planning area shall be comprised of the county of the proposed center and all contiguous Kentucky counties.

   Inpatient and outpatient surgical utilization is computed using an average 2.0 hours (including cleanup time) per inpatient surgery and 1.2 hours (including cleanup time) per outpatient surgery, and 2,205 potential surgical hours per year as follows:

   $$\frac{\text{(Total inpatient operations* x 2.0) + (Total outpatient operations* x 1.2)}}{\text{(Existing and Approved Hospital Operating Rooms** + ASC Operating Rooms**) x 2,205}}$$

   * Shall not include pain procedures performed in a procedure room as reported in the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Services Report.*
   ** Shall not include Cystoscopy rooms as reported in the *Kentucky Annual Ambulatory Surgical Services Report* and the *Kentucky Annual Hospital Utilization and Services Report.*

   Applicants proposing outpatient surgical services may use actual documented surgical time to calculate institution-specific utilization rates. Outpatient operations are the sum of all hospital outpatient and ambulatory surgical center operations;

2. A new ASC shall be located within **twenty (20)** **[~~thirty (30)~~]** [~~twenty (20)~~] minutes normal driving time of at least one (1) acute care hospital;

3. The applicant shall have a transfer agreement for the proposed ASC in place with at least one (1) acute care hospital that is located within **twenty (20)** **[~~thirty (30)~~]** [~~twenty (20)~~] minutes normal driving time of the center;

4. Notwithstanding criterion 1, an application to establish an ASC limited to a specific type of procedure shall be consistent with this Plan if the following conditions are met:

   a. The applicant documents that patients are not receiving the specific type of surgical procedures (as identified by procedure codes) proposed by the applicant at facilities in the planning area; and

   b. The application contains an explanation of why the unmet need for the specific type of surgical procedure has not been reasonably addressed by providers in the planning area;

5. Notwithstanding criteria 1, 3, and 4, an application to establish an ASC limited to ophthalmic surgery procedures shall be consistent with this Plan if the following conditions are met:

   a. The applicant is an ophthalmologist or an ophthalmology group, 100% owned by ophthalmologists, which has been organized and practicing in Kentucky for a period of ten (10) years prior to the date the application was submitted;

   b. The applicant documents that the proposed ophthalmic outpatient surgery procedures have been performed for a period of five (5) years prior to the date the application was submitted;

   c. The applicant documents that prior to March 30, 2016, it has invested no less than $300,000.00 in advanced ophthalmic laser technology;

   d. The proposed ASC is located in the county where the private office is currently located;

   e. Only one (1) ASC shall be established by the applicant; and

   f. The applicant documents that the proposed ASC shall be accredited within twelve (12) months of licensure by the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. (AAAASF), Accreditation Association for Ambulatory Health Care (AAAHC), American Osteopathic Association/Healthcare Facilities Accreditation Program (AOA/HFAP), The Joint Commission (TJC), or another accreditation organization approved by the United States Centers for Medicare and Medicaid Services;

6. Notwithstanding criteria 1, 2, 3, 4, 5, **and** [~~and~~] 7, **[~~and 8,~~]** an application submitted by the license holder of an acute care hospital or critical access hospital that proposes to cease providing inpatient services and transfer existing surgical services to establish an

ASC to be located on the hospital campus or a site within the same county shall be consistent with this Plan; **and** [~~and~~]

7. **[~~Nothwithstanding criteria 1, 4, 5, 6, and 8, an application submitted by a Kentucky-licensed acute care hospital proposing to establish an ambulatory surgical center shall be consistent with this Plan if the following conditions are met:~~**

   ~~a. The ambulatory surgical center shall be located in a county where the applicant hospital does not own one;~~

   ~~b. The ambulatory surgical center shall be located on a site within the same county as the applicant;~~

   ~~c. The ambulatory surgical center shall be located in a county with a population of at least 30,000 residents;~~

   ~~d. The applicant hospital shall be the majority owner (greater than fifty (50) percent).~~

      ~~i. If there is a change of ownership in which the hospital is no longer the majority owner of the ambulatory surgical center after the center is licensed, the hospital shall not be eligible to establish a new ambulatory surgical center under this criterion for a period of not less than five (5) years from the date of the change in ownership.~~

      ~~ii. A hospital shall not be eligible to establish an ambulatory surgical center under this criterion if, within the last five (5) years, the hospital changed from being a majority owner to a minority owner in an existing ambulatory surgical center located in the same county as the hospital;~~

   ~~e. The applicant hospital's overall rating by the Centers for Medicare and Medicaid Services Hospital Compare was four (4) stars or higher for three (3) out of the last four (4) reported quarters preceding the date the application was filed; and~~

   ~~f. The applicant hospital shall be accredited by an accrediting organization approved by the Centers for Medicare and Medicaid Services, including the Joint Commission or another nationally recognized accrediting organization with comparable standards and survey processes; and~~

~~8.~~] Notwithstanding criteria 1, 2, 3, 4, 5, **and** [~~and~~] 6, **[~~and 7,~~]** an application to establish an ASC that does not charge its patients and does not seek or accept commercial insurance, Medicare, Medicaid, or other financial support from the federal government shall be consistent with this Plan if the proposed ASC utilizes the surgical facilities of an existing licensed ASC during times the host ASC is not in operation.

C. Chemical Dependency Treatment Beds

Definition

"Chemical dependency treatment beds" are licensed pursuant to 902 KAR 20:160 and used in the treatment of patients suffering from abuse or addiction to chemical substances such as alcohol or drugs.

Review Criteria

An application for chemical dependency treatment beds shall be consistent with this Plan if the following criteria are met:

1. The number of chemical dependency treatment beds in an ADD shall not exceed a maximum rate of 11.4 beds per 100,000 geographic population for the plan year;

2. Consideration shall be given to the availability of acute care or psychiatric beds designated for use as chemical dependency treatment beds, as well as the availability of KRS Chapter 222 program beds;

3. Applications to develop hospital-based units using existing space shall be given priority over applications requiring new construction; and

4. In ADDs with a rate below the maximum for chemical dependency treatment beds, all or a portion of the bed quota for contiguous ADDs may be used if the applicant demonstrates that:

    a. The proposed facility will be available and accessible to the population or a portion of the population of the contiguous ADDs;

    b. Linkage agreements have been made with appropriate providers in the contiguous ADDs; and

    c. Letters of support have been obtained from any licensed chemical dependency treatment providers in the contiguous ADD.